



## Industry Experts Address Contract Manufacturing Issues

To retain a competitive edge, many businesses are choosing to focus on core competencies and contract external operations for projects requiring supplemental production capacity and/or expertise. For many marketing and manufacturing companies in the dietary supplement industry, contract manufacturers offer advantages over in-house manufacturing including lower costs, flexibility, access to outside proficiencies and reduced capital. However, for expectations to be fully realized, companies must understand what key factors make a contract manufacturing relationship work, as well as what pitfalls to avoid to ensure the intended value is gained from the relationship.

**INSIDER: What are some recent changes or trends in private label manufacturing?**

**John Blanco, president at Bridgeport, Conn.-based AnMar International:** What we have seen is a greater move to outsource production. When a brand company is full in its production line and, thus, needs someone else fill the bill, or when a company wants to concentrate on what it does best (e.g., make tablets and capsules), they leave the granulation, blending and coating work to companies that specialize in those functions.

**Ram Chaudhari, Ph.D., FACN, CNS, senior executive vice president, chief scientific officer at Schenectady, N.Y.-based Fortitech Inc.:** Ingredient suppliers are providing many unique ingredients that deliver specific health condition-related benefits. A few of the top health-related products specifically target digestive health problems, immunity, prebiotics and probiotics, weight management and low glycemic products. These health-targeted ingredients can, and are, being delivered via beverages, snack foods and bars to name a few. They are also routinely coming in more convenient forms as well.

**INSIDER: What are the advantages of using a contract manufacturer versus in-house manufacturing?**

**Lucy MacLoughlin, chief operating officer (COO) at Bellingham, Wash.-based Rhema Industries Inc.:** Using a contract manufacturer may allow companies to focus financial resources on developing brands, marketing and increasing distribution. Creating an in-house GMP (good manufacturing practice) manufacturing facility requires a significant monetary investment in premises, equipment, materials and specialized personnel, and depending on one's business model, this may strain a company's resources and dilute its overall success. Moreover, using a contractor affords access to external expertise, potentially larger purchasing power and, consequently, lower costs.

**Bob White, executive vice president at Sunrise, Fla.-based Nature's Products Inc.:** The benefits of using a contract manufacturer are experience and expertise in all aspects associated with manufacturing, including formulating, quality assurance, raw material sourcing, production and packaging. It takes years to train people in all aspects of production and quality control. In addition, capital equipment is very expensive and it is paramount to have the

necessary production and laboratory equipment needed to provide the functions required to produce efficacious products. While a company may be very successful in marketing products, it does not necessarily translate into the company being able to successfully manufacture and/or package products. Often, a successful marketing company can become distracted when production takes place in-house and what may result is a dilution of management's capabilities to successfully manage both marketing and production.

**Alix Villedrouin, controller for Hauppauge, N.Y.-based Bactolac Pharmaceutical:** A focused and specialized high-quality contract manufacturer is generally better able to stay current with ever-changing quality regulations, monitor raw materials availability and quality trends, and can therefore produce high quality products in a cost-effective and timely manner.

**Tim Gamble, vice president of sales and marketing at Redmond, Wash.-based Nutraceutix Inc.:** Quality contract manufacturers should offer clients a variety of advantages over in-house manufacturing including lower costs through economies of scale and, for specialized products, access to expertise, optimized processes and technologies that are required for the production of very high-quality products.

**INSIDER: What are key considerations to make when deciding whether to outsource manufacturing processes?**

**White:** A careful analysis needs to be conducted to ascertain a company's ability to assimilate a manufacturing operation into its current business model without jeopardizing that existing business model. While cost-savings may appear to be evident on the surface, one must also consider other less-obvious issues such as: product liability insurance cost, manufacturing start-up costs, raw material inventory costs, personnel hiring/training costs and capital expenditure costs.

**MacLoughlin:** The scope of a company's business model and resource base are hugely determinative. Assuming there is a desire for some in-house production, companies should begin with dosage forms that require fewer and/or less complex manufacturing processes such as powders and capsules. It makes the most sense to outsource products that are process and equipment intensive, and that may require specialized expertise, as well as those for which contractors that are strong in particular product categories can offer economies of scale.

**Kenn Israel, vice president of marketing for Los Angeles-based Soft Gel Technologies:** Some considerations include: Will the product profits justify the expense of the human and physical capital required to produce it? Are the opportunity costs of producing the product greater than the potential gain of investing the same effort into your mission critical tasks? Can an outside vendor complete the project/product significantly better than a self-sourced effort? Are technologies and productive processes only available from a contact manufacturer that will make the product more desirable to the market?

**Bob Olson, director of national accounts for Sparta, Wis.-based Century Foods International:** Quality and quality control measures should be high priorities. Businesses need to determine any certifications their products may require and make sure those assurances are offered by the contract manufacturer.

**INSIDER: What are key considerations when choosing a contract manufacturer?**

**MacLoughlin:** Integrity, quality, reliability, service and fair prices. If integrity forms the core of your contract manufacturer's business philosophy, the other parameters flow naturally from it. A manufacturer with integrity will employ GMPs to ensure quality, and will work in cooperation to achieve agreed-upon lead-times. Communication will be proactive and you should feel confident in the company's knowledge, abilities and commitment to you, the customer. Fair-pricing is the dollar amount that allows both companies to make a reasonable and sustaining profit, and reflects the quality and quantity of materials, testing and processing invested in the product.

**Israel:** Determining factors should be: Is the vendor a specialist in this field? Can the contract manufacturer meet the quality specifications, time demands and price requirements of your project? Can the contract manufacturer provide a unique process, ingredient or technology that will provide a compelling market advantage?

**White:** The main determining factors should be based upon the contract manufacturer's ability to produce and guarantee a high-quality product that not only meets label claim, but also meets or exceeds all regulatory requirements. The company should use the highest quality raw materials available, have an in-house laboratory to confirm the quality of all raw materials and finished products, and be GMP certified. Also, the length of time a contract manufacturer has been in business and its reputation are important factors.

**Gamble:** The actual product or ingredients involved should be a primary factor in the decision on where to manufacture a product. It is important to seek out contract manufacturers with a background in producing the quality products you want to associate with your brand. A good example of this involves the production of probiotics, which requires a great deal of expertise, specialized processes and safeguards that most general purpose manufacturers simply do not possess.

**INSIDER: What are common pitfalls to avoid when choosing a contract manufacturer?**

**Villedrouin:** Avoid selecting a manufacturer simply because it is the low-cost bidder or commits to a much faster turnaround than other contract manufacturers. Make sure whoever is promising to manufacture and deliver product has the wherewithal and reputation to deliver. Also, be cautious, as many poor-quality manufacturers buy sub-standard raw materials and substitute alternative materials to achieve low-cost production and make promises they can not achieve.

**White:** Selecting a contract manufacturer by putting too much emphasis on cost is a critical error. Quality-oriented manufacturers, if quoting on the same formulation and using the same quality ingredients, packaging, etc., should not differ in price by plus or minus 5 percent. If a contract manufacturer provides a quote that is lower by 10 percent or 15 percent from other manufacturers, this should be a warning sign. Not all manufacturers formulate product with the appropriate raw material overages to ensure the product will meet 100 percent of label claim at date of expiration, as required by the Dietary Supplement and Health Education Act (DSHEA); as such, their price may easily be 5- to 10-percent lower due to this factor alone. Also, many contract manufacturers do not have their own in-house laboratories and rely solely on raw material supplier Certificates

of Analysis, which does not guarantee that the finished product does indeed meet label requirements.

**Israel:** Lowest pricing usually indicates a trade-off against timing, ingredient quality or experience. Providing a manufacturer a very clear specification of what the finished product requirements are is key to project success. The less clear a specification is at the beginning of a project, the more likely there will be variation at the end.

**INSIDER: How important is it to a contract manufacturer's business that it adheres to GMPs?**

**Israel:** GMPs are absolutely critical for all aspects of the nutritional manufacturing and packaging business. This is probably most true in a contract manufacturing environment, as the manufacturer is being trusted with the reputation of the marketer. If a contract manufacturer is not third-party GMP certified, the buyer is taking a huge chance with its brand. Federal GMPs should have a beneficial effect on the manufacturing environment in that minimum standards will be mandated.

**Gamble:** GMP adherence and, importantly, registration of GMP adherence through an independent review, such as that conducted by NSF International, is a significant advantage for a contract manufacturer and its clients. With the inevitability of increasing regulations in our industry, those manufacturers who achieve GMP and other standards early in the game will, along with their clients, be the big winners.

**Olson:** GMPs help ensure a safe, quality product. The new FDA (Food and Drug Administration) GMPs for supplements are expected soon. There will be many new requirements some manufacturers will not be able to meet. Some may be forced out of business.

**Villedrouin:** For customers to be comfortable that they are getting high-quality products, adherence to GMPs and the next step of certification with an organization such as the National Nutritional Foods Association (NNFA) is an indicator of the contract manufacturer's ability to manufacture under strict guidelines.

**INSIDER: How can contract manufacturers enhance communication with companies to build stronger, more successful relationships?**

**MacLoughlin:** Manufacturers' account executives should know their clients' product mix well and keep them informed of new and innovative materials, packaging options and formulations to help grow their business. The approach should be proactive with the representative regularly contacting their customers to offer value in terms of new ideas and to resolve any matters that might be concerning the client.

**Olson:** The benefits of working with an outsourcing company are best realized by treating it as a partner, not an outside extension of the company. Make at least one visit to the contract manufacturer's facilities. From there, you can determine comfort levels with its operations and staff.

**Kirk Neal, vice president of operations with Chandler, Ariz.-based Arizona Nutritional Supplements:** Building relationships with key personnel from both companies is essential to success. Contract manufacturers need to be able to tailor their services to each

company's particular needs so that all departments of the company can benefit from the relationship.

**INSIDER: What are the advantages and/or disadvantages of making a legal partnership between a company and a contract manufacturer?**

**Neal:** Putting together a contractual agreement can help a customer clearly define expectations and enable the contract manufacturer a greater flexibility to assist the customer's unique needs. It protects both parties and eliminates many misunderstandings that can get in the way of mutual success.

**Villedrouin:** A clear understanding of the production, buying and mutual expectations and obligations in a manufacturing relationship through a written agreement is essential to avoiding misunderstandings and surprises in the relationship. In essence, there needs to be a strong partnership understanding so that each party can rely on one another, so long as they are living up to their mutual understandings.

**Olson:** Within a partnership, both companies benefit from success, and both suffer from failure.

**INSIDER: Are products that are seasonal, have unpredictable demand or frequent project changes better candidates for outsourcing than products with more calculable demand and formulation profiles?**

**Neal:** The less predictable demand profiles are often better candidates for outsourcing because it frees a company from continually worrying about capacity and allows company execs to focus on building the brand.

**Villedrouin:** Much depends upon the contract manufacturer's position and commitment in the marketplace. Some contract manufacturers focus on large runs with long lead times in ordering. Others have built a business model around being able to react quickly to rapid turnaround and smaller runs. There will generally be a price difference for the two types of service. Determining these capabilities should be foremost in the mind of an organization seeking a contract manufacturer.

**MacLoughlin:** Outsourcing products with changeable sales velocity is entirely feasible when the relationship between the companies is strong, when their business terms are structured and yet sufficiently flexible to administer products with differing levels of predictability, and when communication is open and proactive.

**INSIDER: How can contract manufacturers help companies improve supply chain performance?**

**Villedrouin:** Early and frequent communication about changing trends in the industry helps a relationship. Also, advice on regulatory and label considerations adds value to a relationship. Advance communication about planned or considered sales promotions and incentives also will allow a contract manufacturer to provide better and more-timely service.

**Neal:** A good contract manufacturer is willing to listen to the customer and provide accurate lead times and delivery dates. With a better understanding of the customer's business model, we can strive to tailor our service to each customer's specific needs. We want the manufacturing process to be the most reliable part of their business.

**Olson:** Offering full-service manufacturing, including research and development, engineering expertise, formulating, testing, blending and packaging in one location improves speed and effectiveness of the supply chain.

**INSIDER: How can contract manufacturers and companies establish effective roles for managing the manufacturing process?**

**MacLoughlin:** The starting point is having well-delineated areas of responsibility and clear expectations. In broad and general terms, the manufacturer should provide industry resources and technical expertise, and the client should clearly and comprehensively communicate its objectives and requirements to the manufacturer. It is essential both parties have a congruent vision of the finished product. The customer needs to provide the manufacturer with complete information including formulation, specifications, intended product positioning, target market, distribution channels, etc. These parameters guide the manufacturer in terms of which material vendors to select, what packaging recommendations to make to the client, etc. If customers have a less developed concept, they can most effectively help manage the manufacturing process by providing specific and timely responses to suggestions and proposals from their manufacturer. As in all other aspects of a marketer/manufacturer relationship, it is a team approach.

**Neal:** It is important to choose a contract manufacturer that is willing to go beyond solely manufacturing the products. Contract manufacturers work with many segments in the industry and can offer novel approaches to meet business needs. It is important for a contract manufacturer to understand customers are unique and custom—just like the formulations.

**Olson:** Effective roles can only be established through communication and understanding each other's needs and expectations including processes, lead times and limitations.

**INSIDER: What are the inherent challenges of manufacturing private label brand products?**

**Blanco:** What has become an issue from time to time is when a manufacturer wants send a label with a shelf-life date that does not mesh with the date of manufacture for whatever reasons. We have overcome this problem by using bar codes on our products that include the shelf-life date.

**Chaudhari:** Some of the big challenges include regulatory environment issues like GRAS (generally recognized as safe) status, cost of developing new ingredients, and the costs associated with developing new safety and effectiveness studies.